milliliters of absolute alcohol, warming if necessary. Dilute the solution to 25 milliliters with absolute alcohol and mix thoroughly. Proceed as directed in § 436.210 of this chapter, using a 2.0 decimeter polarimeter tube.

(8) *Melting range.* Proceed as directed in § 436.209 of this chapter.

(9) *Absorptivity.* Proceed as directed in paragraph (b)(1)(ii) of this section except calculate the percent relative absorptivity as follows:

$$\text{Percent relative absorptivity} = \frac{\text{Absorbance of sample} \times \text{weight of standard in milligrams} \times \text{potency of standard in micrograms per milligram}}{\text{Absorbance of standard} \times \text{weight of sample in milligrams} \times 10}$$

(10) *Crystallinity.* Proceed as directed in § 436.203(a) of this chapter.

[39 FR 19166, May 30, 1974, as amended at 45 FR 16476, Mar. 14, 1980; 45 FR 64568, Sept. 30, 1980; 48 FR 3960, Jan. 28, 1983; 50 FR 19921, May 13, 1985]

§ 455.11 Chloramphenicol palmitate.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Chloramphenicol palmitate is the white to grayish-white, tasteless palmitic acid ester of chloramphenicol. It is so urified and dried that:

(i) It contains not less than 555 micrograms nor more than 595 micrograms of chloramphenicol per milligram.

(ii) [Reserved]

(iii) Its melting range is 91°±4° C.

(iv) Its specific rotation in absolute ethyl alcohol at 25° C. is +23°±2°.

(v) It is crystalline.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5(b) of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for chloramphenicol content, melting range, specific rotation, and crystallinity.

(ii) Samples required: 10 packages, each containing approximately 500 milligrams.

(b) *Tests and methods of assay*—(1) *Chloramphenicol content.* Proceed as directed in § 436.335 of this chapter.

(2) [Reserved]

(3) *Melting range.* Proceed as directed in § 436.209 of this chapter.

(4) *Specific rotation.* Accurately weigh approximately 1.25 grams of sample in a 25-milliliter, glass-stoppered volumetric flask and dissolve in about 15 milliliters of absolute alcohol, warming if necessary to effect solution. Bring the solution to 25° C. Dilute the solution to 25 milliliters with absolute alcohol and mix thoroughly. Proceed as directed in § 436.210 of this chapter, using a 2.0-decimeter polarimeter tube.

(5) *Crystallinity.* Proceed as directed in § 436.203(a) of this chapter.

[39 FR 19166, May 30, 1974, as amended at 49 FR 6093, Feb. 17, 1984; 50 FR 19921, May 13, 1985]

§ 455.12a Sterile chloramphenicol sodium succinate.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Chloramphenicol sodium succinate is the light-yellow, water-soluble, ethanol-soluble sodium salt of the 3-monosuccinate ester of chloramphenicol. It is so purified and dried that:

(i) Its potency is not less than 650 and not more than 765 micrograms per milligram. If it is packaged for dispensing, its potency when reconstituted as directed in the labeling is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of milligrams of chloramphenicol per milliliter that it is represented to contain.

(ii) It is sterile.

(iii) It is nonpyrogenic.

(iv)—(v) [Reserved]

(vi) Its moisture content is not more than 5.0 percent.